Venable, Bristow

From: Carchman, Loreen
Sent: Wednesday, August 29, 2001 10:15 AM
To: Osborne, Kevin (PMMC Legal)
Cc: Venable, Bristow; Oey, Jan
Subject: RE: Contract Language for Main TES

I received their quote for the first contract. I will bring it over this am.

-L

-----Original Message-----
From: Osborne, Kevin (PMMC Legal)
Sent: Wednesday, August 29, 2001 9:14 AM
To: Carchman, Loreen
Cc: Venable, Bristow; Oey, Jan
Subject: RE: Contract Language for Main TES

Loreen-

Any further input from Covance?

Also, I suggest you all develop a clear internal timeline to execution by 10/1, w/ accountabilities for each step and w/ input from various internal functions such as RM, Purchasing, Finance and us. I suggest developing as soon as practical.

For example, a necessary prerequisite for Bristow and I to provide a draft contract for internal review is a clear, detailed description of services w/ necessary attachments and timelines (WSA) and compensation (WSA, Finance and Purch.). Pls. let me know when ready. I suggest that you all use the various TES materials publicly discussed and planned publications for descriptions.

Also, we need a clear description of the roles of third parties in this TES, e.g., MDS, any Covance subcontractors, etc. It's not too early to begin mapping out for TES itself, e.g., medical professionals subcontracted by Covance.

Also, I suggest detailing the contract process, internally and w/ Covance, for the main study (2nd agmt.).

thanks

-----Original Message-----
From: Carchman, Loreen
Sent: Monday, August 20, 2001 11:33 AM
To: Osborne, Kevin (PMMC Legal)
Cc: Venable, Bristow; Oey, Jan
Subject: RE: Contract Language for Main TES

Here is the tentative timeline. If it gets revised by Covance, I will let you know.

-L

<< File: Key milestones for Main TES.doc >>

-----Original Message-----
From: Osborne, Kevin (PMMC Legal)
Sent: Friday, August 17, 2001 5:00 PM
To: Carchman, Loreen
Cc: Venable, Bristow; Oey, Jan
Subject: RE: Contract Language for Main TES

As w/ other agmts., I suggest a full timeline be developed so this date can be met. When can this be done?

Source: https://www.industrydocuments.ucsf.edu/docs/rgdj0001

-----Original Message-----
From: Carchman, Loreen
Sent: Friday, August 17, 2001 9:15 AM
To: Osborne, Kevin (PMMC Legal)
Cc: Venable, Bristow; Oey, Jan
Subject: RE: Contract Language for Main TES

We would like to have this first contract signed by 10/01/01. Covance is in the process of putting together a scope of work and budget. Once this is received, we can move forward on this first draft.

-L

-----Original Message-----
From: Osborne, Kevin (PMMC Legal)
Sent: Thursday, August 02, 2001 11:14 AM
To: Carchman, Loreen
Cc: Oey, Jan; Venable, Bristow
Subject: RE: Contract Language for Main TES

Loreen-

I suggest we arrange a meeting w/ John R. et al. to discuss. Also, what's the timeline of the proposed first contract re development, etc.?

thanks

-----Original Message-----
From: Carchman, Loreen
Sent: Wednesday, August 01, 2001 8:49 AM
To: Osborne, Kevin (PMMC Legal); Venable, Bristow
Cc: Oey, Jan
Subject: FW: Contract Language for Main TES

Kevin,

Here is the proposed timeline for the TES study.

-L

-----Original Message-----
From: Jill Schultz [SMTP:jill.schultz@Covance.Com]
Sent: Sunday, July 08, 2001 9:45 PM
To: Loreen.L.Carchman@pmusa.com
Cc: Jan.Oey@pmusa.com; Roger.A.Walk@pmusa.com
Subject: Contract Language for Main TES

Dear Loreen,

Attached is an example of a Phase II-III contract and an Investigator Agreement for reference in preparing the draft contract for the main TES. We would suggest that two contracts be prepared, one for study design/feasibility and one for the actual study. The first contract could be prepared and signed rather quickly I would think.

The following draft timeline was provided in my minutes of Jan's visit to Covance on 05/10/01:

End of 11/01 Power analysis completed to determine no. of subjects, visits, biomarkers, etc.
End of 11/01 Begin site selection
03/01/02 Protocol milestones finalized
04/15/02 Draft protocol to PM for review (2-week turn around on review)

Source: https://www.industrydocuments.ucsf.edu/docs/rgdj0001

05/15/02 Final protocol
06/16/02 Contract signed (PM and subcontract with individual sites)
06/15/02 Investigator Meeting
07/15/02 Lead site to start enrollment
09/15/02 Remaining sites to complete start of enrollment

Please let me know if you would like me to set up a conference call to discuss further.

Best regards,

Jill

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If you have received this e-mail transmission in error, please reply to the sender, so that we can arrange for proper delivery, and then please delete the message from your inbox. Thank you. << File: Phase II-III contract 1-29_2.doc >> << File: invagre2_2.doc >>

Source: https://www.industrydocuments.ucsf.edu/docs/rgdj0001